

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA**

GILEAD SCIENCES, INC. and  
EMORY UNIVERSITY,

Plaintiffs,

v.

MYLAN INC. and MYLAN  
PHARMACEUTICALS INC.,

Defendants.

Civil Action No. 1:14-cv-99 (IMK)

**PLAINTIFFS' REPLY MEMORANDUM IN SUPPORT OF OBJECTIONS TO  
MAGISTRATE JUDGE KAULL'S ORDER/OPINION DENYING MOTION TO  
COMPEL RELEVANT DISCOVERY**

At no point in its 10-page Opposition Brief does Mylan even mention – let alone seek to defend – the Magistrate Judge's stated basis for denying Plaintiffs' motion to compel: his understanding that evidence relevant to Mylan's belated nonenablement defense is limited as a matter of law to "the four corners of initial patent and patent application." Order/Opinion at 3. Mylan does not, and cannot, defend that ruling because, respectfully, it is clearly erroneous.

Mylan instead seeks to preserve the erroneous ruling by putting forth two different arguments.

Mylan argues that seeking discovery of any evidence that post-dates the filing date of a patent "vitiates U.S. patent law," and further argues (in bolded, italicized language) that, "if Plaintiffs' position were the law, then no patent could ever be found invalid for lack of enablement." Mylan's Opp. at 3. According to Mylan, "[t]here is no such authority." *Id.* at 2. But, as explained below, Mylan's argument is as wrong as it is hyperbolic.

There is in fact settled authority for the proposition that post-filing evidence of enablement can be relevant to the fact-intensive issue of whether the patent was enabling as of the filing date. That is particularly so when, as here, there is no evidence at all that the ability to practice the invention after the filing date relied on any developments in the art arising after the filing date. At a minimum, such evidence is “reasonably calculated to lead to the discovery of admissible evidence,” which is all Plaintiffs are obligated to demonstrate. After all, despite Mylan’s overwrought language, this is merely a discovery motion and, as this Court has repeatedly recognized, “the discovery rules are given ‘a broad and liberal treatment.’” *Small v. Ramsey*, 2011 WL 3627271, at \*3 (N.D. W. Va. Aug. 17, 2011) (Kaull, M.J.); *see also Hager v. Graham*, 267 F.R.D. 486, 490-91 (N.D. W. Va. 2010) (Seibert, M.J.).

Mylan further argues that Plaintiffs are asking this Court to “forgive their six-month delay” in moving to compel the narrow set of documents at issue. Mylan’s Opp. at 1. Plaintiffs are doing no such thing. Local Rule 37.02(b), on which Mylan relies, expressly excepts parties from its usual requirement that motions to compel be filed within 30 days if the delay is due to “some action of the non-moving party.” N.D. W. Va. L.R. Civ. P. 37.02(b). And that is precisely what happened here. Until June 18, 2015 – a mere *eight days* before Plaintiffs asked this Court to compel the production of the PEPFAR documents – Mylan had simply invoked 35 U.S.C. § 112 and/or the word “enablement” as defenses. *See, e.g.,* Answer, Defenses, and Countercls. of Defs. Mylan Pharmaceuticals Inc. and Mylan Inc. to Pls.’ Second Am. Compl. ¶ 99 (Dkt. No. 97) (asserting that “[o]ne of more claims of the ’245, ’396, ’397, and ’264 patents are invalid for failure to satisfy one or more of the conditions for patentability contained in 35 U.S.C. §§ 101, 102, 103, 112 and/or 116, and/or for obviousness-type double patenting”). To suggest, as Mylan does to this Court, that such *pro forma* language put Plaintiffs on notice of the

specifics of *any* of its invalidity defenses – let alone the details of the nonenablement defense that Mylan withheld from Plaintiffs until the last day of discovery – strains credulity. Yet, remarkably, Mylan now asks this Court to endorse those tactics.

The Court should decline that invitation and grant Plaintiffs’ limited motion to compel.

**A. Contrary to Mylan’s Assertion, Post-Filing Evidence Is Relevant to Enablement, and Discovery of Such Evidence Is Therefore “Reasonably Calculated to Lead to the Discovery of Admissible Evidence”**

Mylan argues that, because enablement is determined “as of the filing date,” it is therefore categorically impossible for any post-filing evidence to be “reasonably calculated to lead to the discovery of admissible evidence.” Mylan goes even further, declaring that seeking such evidence “vitiates U.S. patent law” and “defies common sense.” Mylan’s Opp. at 3. It then baldly asserts to this Court that “[t]here is no such authority.” *Id.* at 2.

Mylan is wrong.

The Federal Circuit has in fact declared that post-filing evidence is at least potentially relevant to the issue of enablement, particularly when, as here, there is no indication that the post-filing work relied on after-developed advances in the art. *See Plant Genetic Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1344 (Fed. Cir. 2003) (“the district court properly used later reports as evidence of the state of the art existing in 1987”) (citing *In re Hogan*, 559 F.2d 595, 605 (C.C.P.A. 1977) (“This court has approved use of later publications as evidence of the state of art existing on the filing date of an application. . . . The difference may be described as that between the permissible application of later knowledge about art-related facts existing on the filing date and the impermissible application of later knowledge about later art-related facts . . . which did not exist on the filing date”)); *see also Eli Lilly & Co. v. Teva Pharm. USA, Inc.*, 609 F. Supp. 2d 786, 807-08 (S.D. Ind. 2009) (post-filing date test results relevant to enablement).

In addition to simply denying its existence, Mylan attempts to circumvent this clear case

law by making a series of factual assertions unsupported by any actual evidence:

- “Mylan’s PEPFAR product is different from the Mylan product accused of infringement in this case.” Mylan’s Opp. at 8.
- “Mylan was not trying to follow the teachings in Plaintiffs’ patents when developing its PEPFAR product.” *Id.* at 9.
- “Mylan was not using Plaintiffs’ patent application when developing its PEPFAR product . . . .” *Id.* at 10.

But the Court will look in vain for any citations to the record of this case in support of these various factual assertions because there are *no* such facts in the case record: Mylan has refused to provide discovery relating to its PEPFAR products beyond some limited testimony from its Rule 30(b)(6) designee. Neither Plaintiffs nor this Court should be obligated simply to take Mylan’s word for it. In fact, what limited evidence Plaintiffs have been able to obtain on this topic strongly suggests that its PEPFAR products would fall squarely within the scope of the asserted Gilead patents. Deshmukh Tr. at 147:16-150:13.

Mylan’s (equally unsupported) assertion that it developed its PEPFAR product for use in other countries “under different regulatory and patent guidelines than those applicable to the instant case,” Mylan’s Opp. at 10, completely misses the mark. It is simply irrelevant what “regulatory and patent guidelines” applied to that product when it was made; what is relevant is whether, in fact, that product falls within the scope of the asserted patent claims, and whether Mylan was able to produce it following the teaching of those patents, without undue experimentation and without relying on after-developed advances in the art. Plaintiffs are entitled to discovery on this issue.

Finally, Mylan’s legal argument that “the accused product is not relevant to enablement,”

*id.* at 7, is likewise simply irrelevant – the PEPFAR product about which Plaintiffs seek discovery is not an “accused product,” as Mylan itself admits in the very next paragraph of its brief (although again without any factual support). *Id.* at 8. (“Mylan’s PEPFAR product is different from the Mylan product accused of infringement in this case.”). The question is not infringement of the PEPFAR product, but whether it is relevant evidence to Mylan’s enablement defense.

Based on the limited information Mylan has made available to Plaintiffs, they have reasonable grounds to believe that Mylan was able to make its PEPFAR product following the teachings of the asserted patents and without relying on after-developed advances in the art. Mylan should therefore be ordered to produce the limited set of requested documents so that Plaintiffs can seek to confirm those facts, and to determine whether Mylan was able to practice the claims of the asserted patents without undue experimentation. At the very least, Plaintiffs’ request for such documents is “reasonably calculated to lead to the discovery of admissible evidence.”

#### **B. Plaintiffs’ Motion to Compel Was Timely**

Mylan’s timeliness argument is premised on the untenable position that the mere rote incantation of an “enablement” defense in its answer and counterclaims (along with a list of nearly every other defense articulated in 35 U.S.C.) should have been sufficient to put Plaintiffs on notice of the specifics of its nonenablement argument – details Mylan withheld from Plaintiffs until June 18, 2015, the very last day of fact discovery. *See, e.g., Heidelberg Harris, Inc. v. Mitsubishi Heavy Indus., Ltd.*, 1996 WL 680243, at \*6-8 (N.D. Ill. Nov. 21, 1996) (general notice of defendant’s intent to assert a § 112 defense in answer and interrogatory response insufficient to permit specific defense to be presented at trial). Yet Mylan has still not explained

precisely how, and on what basis, Plaintiffs were to anticipate these undisclosed specifics before finally being set forth by Mylan.

Mylan did not articulate any specific nonenablement argument until (literally) the eve of the close of discovery. Moreover, Mylan did not substantially complete its document production until after the close of discovery, producing the vast majority of its documents in the final two weeks of that long-delayed production. Mylan now seeks to benefit from those tactics. Endorsement by this Court would only encourage such tactics in the future.

Mylan itself made these documents relevant to this case by injecting its specific nonenablement argument into the case on the last day of discovery. Should it be permitted to continue to pursue such a belated theory, it should at least be required to produce relevant, requested documents. Fairness calls for nothing less.

Plaintiffs raised this issue with the Court promptly, filing its brief seeking an order compelling Mylan's production of the PEPFAR documents a mere eight days after Mylan first provided Plaintiffs the details of its theretofore generic "enablement" defense. Any delay beyond those eight days is directly attributable to Mylan's tactical decision to withhold any details of its nonenablement defense until June 18, 2015. That additional delay falls squarely within the explicit exception to the 30-day limitation for motions to compel in Local Rule 37.02(b), given that the delay was due to "some action of the non-moving party." N.D. W. Va. L.R. Civ. P. 37.02(b).

### **C. Conclusion**

The scope of permitted discovery is broad and liberal. Plaintiffs' motion seeks production of a limited set of documents that are reasonably calculated to lead to the discovery of admissible evidence.

The Magistrate Judge denied Plaintiffs' motion on legal grounds that Mylan has implicitly acknowledged were clearly erroneous. The Federal Circuit has made clear that evidence that the invention taught in a patent can be practiced after the filing date without undue experimentation and without use of after-developed advances in the art can be relevant to the enablement inquiry. Mylan has presented no facts to the contrary, only unsupported attorney argument.

Plaintiffs raised this issue with the Court promptly, only eight days after Mylan first disclosed the previously withheld details of its nonenablement defense. Any delay beyond those eight days was due entirely to Mylan's own (in)action.

Plaintiffs' Objections to the Magistrate Judge's July 1, 2015 Order/Opinion should be granted and Mylan should be ordered to produce promptly the requested PEPFAR documents.

Dated: August 4, 2015

Respectfully submitted,

/s/Chad L. Taylor

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**CERTIFICATE OF SERVICE**

I hereby certify that on August 4, 2015, the foregoing **PLAINTIFFS' REPLY MEMORANDUM IN SUPPORT OF OBJECTIONS TO MAGISTRATE JUDGE KAULL'S ORDER/OPINION DENYING MOTION TO COMPEL RELEVANT DISCOVERY** was served upon the attorneys of record for Defendants Mylan Inc. and Mylan Pharmaceutical, Inc. via the Court's CM/ECF system, which will send electronic notification of the filing to the counsel of record for Defendants.

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